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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/296,031	04/21/99	LYONS PH.D.	S D6218

HM12/0809

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EXAMINER	
CHEN, S	
ART UNIT	**PAPER NUMBER**
1633	4

DATE MAILED: 08/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/296,031	Lyons et al.
Examiner	**Group Art Unit**
Shin-Lin Chen	1633

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-14 is/are pending in the applicat

Of the above, claim(s) 1-6 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 7-14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 3.

2. Applicant's election with traverse of group II, claims 7-14, in Paper No. 3 is acknowledged. The traversal is on the ground(s) that both groups I and II are based on the observation that chlorotoxin specifically binds to tumors of neuroectodermal origin and this specificity provides the inventive quality to both groups. This is not found persuasive because groups I and II are drawn to different scientific considerations: group I requires preparation of a fusion protein containing chlorotoxin and a cytotoxic moiety, delivery of said fusion protein to a subject so as to provide therapeutic effects for a neuroectodermal tumor in a subject *in vivo*. Group II requires preparation of a labeled chlorotoxin for the detection of a neuroectodermal tumor to differentiate from non-neoplastic tissue *in vitro*. Thus, they are patentably distinct and drawn to different classifications. They require separate searches.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 7-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-9 of U.S. Patent No. 5,905,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although drawn to different scope, they encompass the same invention and obvious variants thereof.

Claims 7-14 of the present application are drawn to a method of differentiating neuroectodermal tumor-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a detection moiety, such as fluroschrome, biotin, or a colorimetric agent linked to an enzyme substrate. Claim 10 specifies the chlorotoxin binding is determined by fluorescent microscopy, ELIZA or fluorescent activated cell sorting (FACS). Claims 11-14 specify the chlorotoxin is radiolabeled,

such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning.

Claims 3-9 of '027 are drawn to a method of differentiating glial-derived or meningioma-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a fluorescent moiety. Claim 8 specifies the chlorotoxin binding is determined by fluorescent microscopy or fluorescent activated cell sorting (FACS). Claims 5, 6 and 9 specify the chlorotoxin is radiolabeled, such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning.

Glial-derived or meningioma-derived neoplastic tumor tissues are encompassed by the neuroectodermal tumor-derived neoplastic tumor tissues. Therefore, it would have been obvious for one of ordinary skill at the time of the invention to practice the claimed invention according to the teachings of '027. Thus, claims 7-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-9 of U.S. Patent No. 5,905,027.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 7-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sontheimer et al., 1997 (N).

Claims 7-14 are drawn to a method of differentiating neuroectodermal tumor-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a detection moiety, such as fluroschrome, biotin, or a colorimetric agent linked to an enzyme substrate. Claim 10 specifies the chlorotoxin binding is determined by fluorescent microscopy, ELIZA or fluorescent activated cell sorting (FACS). Claims 11-14 specify the chlorotoxin is radiolabeled, such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning.

Sontheimer teaches a method of differentiating glial-derived or meningioma-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a fluorescent moiety and the chlorotoxin binding is determined by fluorescent microscopy or fluorescent activated cell sorting (FACS). Sontheimer

also teaches that the chlorotoxin is radiolabeled, such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning (e.g. p. 54, 55). Thus, claims 7-14 are clearly anticipated by Sontheimer.

7. Claims 7-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Ullrich et al., US Patent No. 5,905,027 (A).

Claims 7-14 are drawn to a method of differentiating neuroectodermal tumor-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a detection moiety, such as fluroschrome, biotin, or a colorimetric agent linked to an enzyme substrate. Claim 10 specifies the chlorotoxin binding is determined by fluorescent microscopy, ELIZA or fluorescent activated cell sorting (FACS). Claims 11-14 specify the chlorotoxin is radiolabeled, such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning.

Ullrich teaches a method of differentiating glial-derived or meningioma-derived neoplastic tumor tissue from non-neoplastic tissue comprising contacting a tissue of interest with labeled chlorotoxin and an elevated level of chlorotoxin binding indicates the tissue is neoplastic, wherein the chlorotoxin is labeled with a fluorescent moiety and the chlorotoxin binding is

determined by fluorescent microscopy or fluorescent activated cell sorting (FACS). Ullrich also teaches that the chlorotoxin is radiolabeled, such as ^{131}I-chlorotoxin or ^{125}I-chlorotoxin, and the radiolabeled chlorotoxin binding affinity is from 5 nM to about 5 uM determined by positron emission tomography scanning (e.g. column 25, 26). Thus, claims 7-14 are clearly anticipated by Ullrich.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Deborah Clark

DEBORAH J.R. CLARK
PRIMARY EXAMINER

Shin-Lin Chen, Ph.D.